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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,891	11/17/2000	Susan R. Webb	TSRI 536.1Div2	7205

7590 07/15/2002

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EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/15/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/715,891

Applicant(s)

WEBB ET AL.

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 61-82, and the species HLA BP alpha and beta chains, a cosombination of costimulatory molecule and adhesion molecule, B71.1 and ICAM, an insect cell, and drosophila in Paper No. 8, filed 4-26-02, is acknowledged.

The traversal is on the ground(s) that the generic claims recite a multiplicity of species that do not require an unduly extensive and burdensome search. This is not found persuasive because each of the species of the generic synthetic antigen presenting matrix recited in the generic claims encompasses a matrix of different components. As such, though the searches for each species overlap somewhat, said searches are not co-extensive and as such would constitute an undue burden to the examiner as outlined in the restriction requirement mailed 3-26-02, Paper No. 7.

However, since no prior art was found on the elected species, nor on any of the recited or disclosed species encompassed by the instant claims, the species requirement has been withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

3. New formal drawings are required in this application because of the reasons stated in the attached PTO Form 948. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front

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of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability."

Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

3. Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Specification

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Priority

5. **Regarding claims 62-63, 65-67, 70, 74-76 and 79-82 only**, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994).

Applicant is invited to point out support in said provisional for said claims.

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Oath/Declaration

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
the priority data listed in the oath is not consistent with the priority data listed in the first line of the specification; specifically, there is no mention of 09/194,285 in the oath.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61-84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a method of producing a synthetic antigen presenting cell (APC) comprising transforming a cell with MHC Class II alpha gene and beta gene and an accessory molecule gene. The instant disclosure of "a synthetic antigen presenting cell" and "accessory molecule gene" do not adequately describe the scope of each claimed genus, each of which encompasses a substantial variety of subgenera. With the exception of insect cells and the genes encoding the accessory molecules of B71.1, B71.2, ICAM-1, ICAM-2 ICAM-3, FASL, CD70 and LFA, there is no description in the instant specification of the required structural and specific functional features of said broad genus of synthetic antigen presenting cells that would meet the recited limitations of antigen presenting cell. Neither is there a disclosed description of the structural features that would be attributed to an accessory molecule. Further, the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the synthetic antigen presenting cells or accessory molecules encompassed by the instant claims, with the exception of insect cells and the accessory molecules of B71.1, B71.2, ICAM-1, ICAM-2 ICAM-3, FASL, CD70, and LFA, as disclosed in the instant specification on page 8, lines 18-19. Therefore, the structure of "a synthetic antigen presenting cell" and "accessory molecule gene" is not conventional in the art and one of skill in the art would not recognize from the disclosure that applicant was in possession of the genus of "a

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synthetic antigen presenting cell" and "accessory molecule gene" encompassed by the method of the claimed invention.

It is noted that though the claimed invention encompasses cells as well as genes, and not cDNA, the principle of the following still holds for said cells and genes : a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.)

8. Claims 61-82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing a synthetic antigen presenting cell comprising an insect cell and the accessory molecules of B71.1, B71.2, ICAM-1, ICAM-2 ICAM-3, FASL, CD70 and LFA , does not reasonably provide enablement for said method comprising any cell, nor any accessory molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant claims are drawn to a method of producing a synthetic antigen presenting cell (APC) comprising transforming a cell with MHC Class II alpha gene and beta gene and an accessory molecule gene.

The instant claims therefore read on cells from sources as diverse as plants, prokaryotes and mammalian cells. The instant specification exemplifies cells and vectors from the insect species and provides guidance for transfecting insect cells with MHC subunits and accessory molecules of B71.1, B71.2, ICAM-1, ICAM-2 ICAM-3, FASL, CD70 and LFA . However the instant specification is not enabling for the transfection and use of other types of cells for reasons disclosed on page 8 which include that MHC Class II molecules have been expressed in insect cells, and that insect cells do not have a mammalian peptide loading machinery nor class II molecules, therefore allowing the introduced mammalian MHC class II molecules to be expressed as empty molecules at the cell surface, allowing specific peptides to be loaded into specific MHC Class II molecules at room temperature. Without further guidance from the specification it would require undue experimentation for one of skill in the art to predict which cells other than insect cells, would be effective in a synthetic antigen presenting cell.

The instant specification discloses on page 17 that accessory molecules broadly include co-stimulatory molecules, adhesion molecules and survival molecules and the like. Janeway et al (Immunobiology 1997) teaches only the accessory molecules of other B71.1, B71.2, ICAM-1,

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ICAM-2 ICAM-3, FASL, CD70 and LFA are involved in antigen presentation (see pages 7:6, 7:8 and 7:25). However, neither the specification nor the prior art teaches accessory molecules (known and unknown) involved in antigen presentation other B71.1, B71.2, ICAM-1, ICAM-2 ICAM-3, FASL, CD70 and LFA. Without further guidance from the specification it would require undue experimentation for one of skill in the art to predict which accessory molecules other than B71.1, B71.2, ICAM-1, ICAM-2 ICAM-3, FASL, CD70 and LFA, would be effective in a synthetic antigen presenting cell.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 61-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 60-80 are indefinite in the recitation of "APC". The instant claims refer to APC as and antigen presenting cell. However, the instant specification discloses on pages 5-6 that a synthetic antigen presenting system is also referred to as APC, and that said system encompasses a synthetic antigen presenting matrix having a support and at least the extracellular portion of a MHC Class II heterodimeric molecule and an accessory molecule linked to the support. Clarification is required.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

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Amy DeCloux, PhD.

Patent Examiner, Group 1640,

July 14, 2002

Amy DeCloux
7-15-02